



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/069,307

09/26/2002

Edward Ingenito

ATX-011.03

1962

25181

7590

09/15/2008

FOLEY HOAG, LLP
PATENT GROUP, WORLD TRADE CENTER WEST
155 SEAPORT BLVD
BOSTON, MA 02110

EXAMINER

VU, QUYNH-NHU HOANG

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

09/15/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/069,307	Applicant(s) INGENITO, EDWARD	
	Examiner QUYNH-NHU H. VU	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 July 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-34,55-58,60-63 and 65-73 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-34, 55-58, 60-63, 65-73 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 3763

DETAILED ACTION

Response to Amendment

Amendment filed on 7/9/08 has been entered.

Claims 1, 3-34, 55-58, 60-63, 65-73 are present for examination.

Claims 2, 35-54, 59, 64 are cancelled.

Specification

The Specification of this application is missing. Examiner requests that Applicant re-sends another Specification.

For examining purpose, the Examiner gets the information from the relate application number 10/649232 (US 2004/0038868).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1- 3, 13-16, 18-19, 24, 31-34, 55-58, 60-63, 65-67, 69-72 are rejected under 35 U.S.C. 102(e) as being anticipated by Perkins et al. (US 6,287,290).

Perkins discloses a methods and systems and kits for lung volume reduction that comprising: advancing a bronchoscope/catheter in to a region of a lung targeted (DR, see Fig. 4-6) for reduction in a patient (col. 2, lines 15-20, col. 8, lines 18+);

introducing material (gases/liquids/fibrin) through the bronchoscope into a diseased alveolar region within the targeted region (col. 2, lines 29-43, col. 3, line 24-32, col. 10, lines 37+); Perkins further discloses that the method of his invention can be comprises sealing or occluding the air passage leading

Art Unit: 3763

to the collapsed tissue region/reduce the volume of the targeted region within the patient's lung; the sealing can be performed in variety of ways, including adhesion, gluing, and the like (col. 10, lines 37-41).

wherein the material (fibrin glue if the sealing method is applied) introduced through the bronchoscope induces collapse of the targeted region (col. 2, lines 30-35, col. 3, lines 22-58); promotes adhesion between one collapsed portion of the lung and another; and promotes fibrosis /fibrin glue in or around the collapsed region of the lung (col. 2, lines 37-43, col. 4, lines 10-20).

Regarding claims 13, 19, suitable plugs include swellable collagen matrices which hydrate and expand within the air passage so that they fully occlude/block the passage (col. 2, lines 34-38).

Regarding claims 14-15, 24, Perkins discloses a method comprising: collapse the diseased alveolar region by aspiration air, and any other gases or liquids that maybe introduced; adhere (sealing/adhesive) one portion of collapsed region to another, and promoting fibrosis (fibrin glues) in or around the collapsed region of the lung; the method is performing using a bronchoscope/catheter.

Regarding claims 16 and 18, Perkins discloses that sealing or occluding the air passage leading to the collapsed tissue region of the lung is achieved by administering a substance (fibrin) that increases the surface tension of fluids lining the alveoli in the targeted region (col. 10, line 37+).

Regarding claims 55-58, 60-63, 65-67, 69, 72-73, Perkins discloses the method comprising: introducing a material (seal/ adhesive/fibrin glues or cyanoacrylate into the lung and collapsing the diseased region to reduce the volume of the lung (col. 10, line 35+); blocking air passage by inducing the plugs include swellable collagen (col. 2, lines 34-38), or balloon catheter (Figs. 4-6, 8).

Regarding claim 70, absorbable gas (oxygen rich gas) can be introduced prior to collapsing the region (col. 6, lines 59+, col. 9, line 45+)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

Art Unit: 3763

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6-12, 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Perkins et al.

Perkins meets the claim limitations as described above but fails to disclose the fibrin/fibrinogen comprises component of materials listed in claims 6-12.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the material listed in claims 6-12, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

Claims 4-5, 17, 20-21, 25-27, 29-30, 68, 73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Perkins et al. in view of Edwardson et al. (US 5,739,288).

Perkins meets the claim limitations as described above but fails to disclose the fibrin comprises a polypeptide growth factor, the use of fibrinogen and a fibrinogen activator such as thrombin.

Edwardson discloses a fibrin further comprises a polypeptide growth factor, a fibrin sealant composition that can be used for sealing tracheal and bronchial anastomoses and air leaks or lacerations of the lung (promoting fibrosis) that includes fibrinogen, thrombin, clot promoting factor XIIIa and antibiotics. Since the invention of Perkins is drawn to closing a region of the lung by gluing tissue (see Perkins col. 1, line 40) and Edwardson teaches a composition to enhance the closure of leaks or laceration of the lung (i.e. a tissue sealant) a combination is proper. At the time of the invention, it would have been obvious to use the fibrin sealant of Edwardson in order to provide an enhanced fibrin formulation for tissue closure thereby improving patient recovery times.

Claims 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Perkins et al. in view of Edwardson in further view of Antanavich et al. (US 5,814,022).

Perkins in view of Edwardson meets the claim limitations as described above but fails to include the composition comprising 3-12% fibrinogen.

Art Unit: 3763

Antanavich discloses a method and apparatus for applying tissue sealant that includes that use of an adhesive protein solution having a fibrinogen content of from 3 to 12% with clot promoting factor XIIIa and further notes that one reason for this arrangement is that the strength of the sealant is proportional to the fibrinogen concentration. Since the invention of Perkins is drawn to closing a region of the lung by gluing tissue (see Perkins col. 10, line 40) and Antanavich teaches an enhanced fibrin sealant composition a combination is proper.

It would have been obvious to one having ordinary skill in the art at the time of the invention was made to incorporate the concentration of fibrinogen as taught by Antanavich et al. into the invention of Perkins in order to have an adhesive protein solution that is less prone to clogging before administered to the therapeutic site as taught by Antanavich et al. Furthermore, It would have been obvious to one having ordinary skill in the art at the time of the invention was made to provide the composition of fibrinogen from 3-12%, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art.

Response to Arguments

Applicant's arguments filed 7/9/08 have been fully considered but they are not persuasive.

1. Applicant argues that Applicant's claimed methods relate to reducing lung volume in a patient by introducing material through a bronchoscope into a diseased region. The material does not serve merely as a plug to occlude the air passage leading to the collapsed tissue region as in Perkin.

In response, Examiner explains above that the material (gas/liquid/or even sealing fibrin) is leading to the collapsed tissue region, (col. 2, lines 30+ or see rejection above for more details), while the plugs to occlude/block the air passage.

2. Applicant argues that Perkin does not teach or suggest promoting stable volume reduction of a target region of a patient's lung by introducing a material into a diseased region where the material induces collapse of the targeted region, promotes adhesion between one portion of the lung and another and promotes fibrosis in or around the collapsed region of the lung.

Art Unit: 3763

In response, Perkin clearly discloses that promoting stable volume reduction of diseased region of a patient's lung by inducing a material (gas/liquid or even sealing, adhesive such as fibrin glue) into a diseased region. Since the lung tissue is collapsed, it needs to adhere the lung tissues together such as promotes adhesion (sealing, suturing, gluing, adhesion...); and promotes fibrin glue in the collapsed region of the lung (see Figs. 6, 8, col. 10, line 26+).

3. Applicant argues that Edwardson does not cure the deficiencies of Perkins vis-à-vis the amended claims. Antanavich does not cure the deficiencies of Perkins and Edwardson vis-à-vis the amended claims because the only relevant contribution from Antanavich to the Examiner's obviousness rejection is the disclosure of an adhesive protein solution having a fibrinogen content from 3 to 10%.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to QUYNH-NHU H. VU whose telephone number is (571)272-3228. The examiner can normally be reached on 6:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3763

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763

Quynh-Nhu H. Vu
Examiner
Art Unit 3763